REMARKS

Reconsideration is requested.

Claims 36-77 are pending. Claims 42 and 43 have been withdrawn from consideration. Claim 78 has been added. Claims 36-41 and 44-78 are under active consideration. Basis for new claim 78 may be found, for example, in Example 10, page 30 of the specification. No new matter has been added.

The specification has been amended to include a cross-reference to the parent application PCT/EP99/02547, filed April 15, 1999, which designated the U.S. The indicated PCT application is submitted to have been a U.S. application as of its filing date (i.e., April 15, 1999), and claiming benefit of both the PCT application and EP 98870087.8, field April 17, 1998, is believed to be appropriate. The Examiner is requested to see the originally-filed Declaration of the inventors in this regard. Moreover, a certified copy of the priority document was filed November 22, 2000. The Examiner is requested to acknowledge receipt of the priority document EP 98870087.8 as well as the claim for domestic priority under Section 120, in the Examiner's next Action.

The specification has been amended to include the attached abstract.

Claim 63 and the specification have been amended to provide a further definition of the described Empigen, consistent with the recognized definition for the same. See, attached Calbiochem circular. Withdrawal of the objections to the specification and claims noted on pages 3-4 of the Office Action dated August 9, 2002 (Paper No. 11), are requested.

The Section 112, second paragraph, rejection of claims 36-77, noted on page 4 of Paper No. 11 is submitted to be obviated by the above amendments. Reconsideration and withdrawal of the Section 112, second paragraph, rejection of claims 36-77 is requested.

The Section 112, first paragraph, rejections of claims 76 and 77 noted on pages 5 and 6 of Paper No. 11 are submitted to be obviated by the above amendments. Reconsideration and withdrawal of the Section 112, first paragraph, rejections is requested.

The Section 102 rejection of claims 36-41 and 50-77 over Figard (U.S. Patent No. 5,616,460), is traversed. Reconsideration and withdrawal of the Section 102 rejection are requested in view of the following distinguishing comments.

The applicants submit that Figard (U.S. 5,616,460) discloses buffer compositions that can be used in immunological methods. More specifically, Figard discloses in Figure 1/Example 1 that the stability of the HCV 33c antigen can be maintained under "the most extreme heat stress conditions (37°C for 12 days)", see column 8 lines 23-25. The HCV 33c antigen is constituted by amino acids 1192 to 1457 of the HCV polyprotein (see column 8, lines 47-48). Thus, Figard discloses the stabilizing effect of ethylene glycol, but not of polyethylene glycol, glycerol or polyvinyl acetate, on the HCV 33c antigen (see column 8, lines 4-11). Figard does not disclose a positive effect of ethylene glycol on the sensitivity of detection of antibodies binding to the HCV 33c antigen. Furthermore, Figard does not contemplate, teach or suggest the use of a reducing agent to increase the sensitivity of detection of antibodies binding to the HCV 33c antigen.

In clear contrast therewith, the presently claimed invention provides a kit containing a reduced HCV NS3 antigen which is much more efficient in binding antibodies than a kit wherein said HCV NS3 protein is not reduced.

Reconsideration and withdrawal of the Section 102 rejection of claims 36-41 and 50-77 over Figard are requested.

The Section 102 rejection of claims 36-41 and 50-77 over Seidel (U.S. Patent No. 6,036,579), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

Initially, the applicants respectfully disagree with the Examiner's suggestion that the "step at which reducing agent is added and the step of sulphonation/desulphonation are method steps and are not encompassed in the claimed product" (see, page 7 of Paper No. 11), as the structure and/or properties of the recited protein of the claims is distinct and advantageous as compared to a non-reduced protein or protein which has not been sulphonated/desulphonated. Accordingly, while the claims are directed to products, the recited elements of the claimed products are different from that of the cited art by virtue of their prior treatment.

Furthermore, the invention by Seidel is focused around the advantages of the HCV NS3 antigen described therein (see, e.g., column 1, lines 60-65 and column 3, lines 16-19). Seidel discloses in column 4, lines 47-53, that an immunological test can be carried out under mild reducing conditions by addition of mild reducing agents to the test. Claim 14 of Seidel seems to be based thereon and covers a method, as opposed to a kit, wherein the antibody-containing sample is incubated under reducing conditions with a HCV NS3 polypeptide. It should thus be clear that Seidel are not contemplating

an immunoassay kit carrying on its solid phase an already reduced HCV NS3 antigen, or an HCV NS3 antigen and a reducing agent (i.e. both contrary to a method wherein an antibody-containing sample is contacted with an antigen under reducing conditions).

Reconsideration and withdrawal of the Section 102 rejection of claims 36-41 and 50-77 over Seidel is, therefore, requested.

The Section 102 rejection of claims 39 and 44-49 over Leroux-Roels (WO 95/12677) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

The Examiner is understood to be asserting that SEQ ID NO:18 of the present invention is anticipated by Leroux-Roels (WO 95/12677). It is noted that NS3 sequence in Leroux-Roels (WO 95/12677) which may correspond to (i.e. and not be identical to) SEQ ID NO:18 of the present invention, as well as fragments thereof, are disclosed as peptides having T-cell stimulating properties. Leroux-Roels (WO 95/12677) do not disclose, teach or suggest however to use NS3 sequences (as in claim 5/Figure 6 of WO 95/12677) as an antigen for detection of antibodies, i.e., for inclusion in an immunoassay kit, as presently claimed.

The Section 102 rejection of the claims 39 and 44-49 over Leroux-Roels, therefore should be withdrawn as the reference fails to teach each and every aspect of the presently claimed invention.

Consideration of the attached Information Disclosure Statement and the references included therein and return of an initialed copy of the attached PTO-1449 Form, listing the attached references, are requested, pursuant to MPEP Section 609.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____
B. J. Sadoff
Reg. No. 36,663

BJS:plb
1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

Amendments in a Revised Format Now Permitted

Office of Patent Legal Administration << Pre-OG Notices << <<

The United States Patent and Trademark Office (USPTO or Office) is permitting applicants to submit amendments in a revised format as set forth herein. The revised amendment format is essentially the same as the amendment format that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. The Office plans to adopt such a revision to 37 CFR 1.121 by July of 2003, at which point compliance with revised 37 CFR 1.121 will be mandatory.

The revised amendment format is an expansion of the special amendment process instituted for a prototype Electronic File Wrapper program described in USPTO ANNOUNCES PROTOTYPE OF IMAGE PROCESSING, 1265 Off. Gaz. Pat. Office 87 (Dec. 17, 2002) ("Prototype Announcement"). The special amendment process (which was limited to claims) has proven overwhelmingly acceptable to applicants participating in the prototype and beneficial to examiners. The revised amendment format provides for amendments to be made to the specification and the drawings in addition to the claims.

Effective immediately, **all** applicants, including applicants participating in the prototype, may submit amendments using the revised amendment format set forth herein. Applicants may wish to submit all amendments in the revised amendment format because: (1) it will facilitate transition to a revised amendment format when it becomes mandatory, (2) inconsistent versions of claim amendments (clean and marked-up) will be avoided, and (3) time and resources will be saved.

WAIVER of 37 CFR 1.121

The provisions of 37 CFR 1.121(a), (b), (c) and (d) are waived for amendments to the **claims, specification, and drawings** in all applications in all Technology Centers where the amendments comply with the revised amendment format detailed below. Note: The revised amendment format (and the waiver) does **not** apply to 37 CFR 1.121(h) and (i) which indicate that amendments to reissue applications and reexamination proceedings are governed by 37 CFR 1.173 for reissue applications and 37 CFR 1.530 (d)-(k) for *ex parte* and *inter partes* reexaminations.

In addition, the WAIVER indicated in the above mentioned Prototype Announcement for the limited (claims only) amendment process of that prototype is also expressly continued and amendments in applications (other than reissue applications) in all Technology Centers that comply with the requirements in that announcement will be acceptable.

REVISED AMENDMENT FORMAT

I. Begin Sections on Separate Sheets:
Each section of an amendment paper (e.g., Amendments to the Specification, Amendments to the Claims, Remarks) shall begin on a separate sheet to facilitate separate indexing and electronic scanning of the document.

For example, each of the following four sections of an amendment paper must start on a separate sheet:

a.) Introductory Comments
b.) Amendments to the Specification
c.) Amendments to the Claims
d.) Remarks

I. Submit Only One Version (with markings) of an Amended Part:
The requirement to provide two versions of a replacement paragraph, section, or claim (a clean version and a marked up version), as set forth in current 37 CFR 1.121, is waived where the format set forth below is followed.

III. Amendments to the Claims

A. A Complete Listing of Claims is Always Required:

If an amendment adds, changes or deletes any claim, a detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remains under examination in the application, must be presented, and the amendment to the claims is expressed in the listing. The listing shall be presented as follows:

1. Ascending Order and Status Identifier Required
The listing shall be provided in sequential ascending numerical order (beginning with claim 1). A status identifier shall be provided for every claim in a parenthetical expression following the claim number (e.g., "Claim 1. (original)"). A list of acceptable status identifiers is set forth in part B, below. The text of **all** claims under examination shall be submitted each time any claim is amended. Cancelled and withdrawn claims should be indicated by only the claim number and status. The text of cancelled or withdrawn claims should not be presented.

2. Markings in Currently Amended Claims Required
All claims *being currently amended* shall be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The changes in any amended claim should be shown by strikethrough (for deleted matter) or underlining (for added matter). No separate "clean" version should be submitted for currently amended claims, as this requirement has been eliminated. **Markings should only be made in claims being currently amended in an amendment paper**.

3. Only Clean Text Required for Other Claims Under Examination.
The text of pending claims *not being currently amended* that are under examination shall be presented in a clean version in the listing. Any claim presented in clean version constitutes an assertion that it has not been changed relative to the immediate prior version.

4. Status to Effect Claim Cancellation or Addition.
A claim may be cancelled by merely indicating the status of the claim as cancelled. Any new claim added by amendment must be indicated by the appropriate status identifier and shall not be underlined. Thus, added new claims of status (new), (reinstated - formerly claim #_) and (re-presented - formerly dependent claim #_) must be presented in clean version. Additional claims may be subject to additional fees, as appropriate.

5. When Grouping of Claims is Permitted.
Consecutive cancelled or withdrawn claims may be aggregated into one line of the listing (e.g. Claims 1 - 5 (cancelled)).

6. Use "Currently Amended" Status Where Applicable.
If any "previously reinstated" or "previously re-presented" claim is being amended, the status shall be indicated as "currently amended" with markings as indicated in paragraph A2, above. Multiple status identifiers should not be used for any single claim.

B. Status Identifiers that May be Used:

In order to promote uniformity and consistency, only the following eleven (11) defined status

identifiers should be used to indicate the status of the claims (in parentheses after the claim number):

1. (Original):	Claim filed with the application following the specification (i.e., not added by preliminary amendment).
2. (Currently amended):	Claim being amended in the current amendment paper.
3. (Previously amended):	Claim not being currently amended, but which was amended in a previous amendment paper.
4. (Cancelled):	Claim cancelled or deleted from the application.
5. (Withdrawn):	Claim still in the application, but in a non-elected status.
6. (Previously added):	Claim added in an earlier amendment paper.
7. (New):	Claim being added in the current amendment paper.
8. (Reinstated - formerly claim # _):	Claim deleted in an earlier amendment paper, but re-presented with a new claim number in current amendment.
9. (Previously reinstated):	Claim deleted in an earlier amendment and reinstated in an earlier amendment paper.
10. (Re-presented - formerly dependent claim # _):	Dependent claim re-presented in independent form in current amendment paper.
11. (Previously re-presented):	Dependent claim re-presented in independent form in an earlier amendment, but not currently amended.

C. Example of Listing of Claims:

Claims 1-5 (cancelled)
Claim 6 (withdrawn)
Claim 7 (previously amended): A bucket with a handle.
Claim 8 (currently amended): A bucket with a ~~green~~ blue handle.
Claim 9 (withdrawn)
Claim 10 (original): A bucket with a wooden handle.
Claim 11 (cancelled)
Claim 12 (new): A bucket with plastic sides and bottom.
Claim 13 (previously added): A bucket having a circumferential upper lip.
Claim 14 (re-presented - formerly claim 11): A black bucket with a wooden handle.

IV. Amendments to the Specification

Amendments to the specification are to be made by presenting replacement paragraphs, sections or a substitute specification marked up to show changes made relative to the immediate prior version, as set out in 37 CFR 1.121(b). The changes should be shown by strikethrough (for deleted matter) or underlining (for added matter). No accompanying "clean" version shall be supplied. The amendments to the specification shall be presented only one time, and will not appear in successive amendment documents.

V. Amendments to the Drawings

Amendments to the drawing figures shall be made by presenting replacement figures which include the desired changes, without markings, and which comply with § 1.84. The changes shall be explained in the accompanying remarks section of the amendment paper. If the amended drawings are not approved, the applicant will be notified in the next Office action. Any amended drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even though only one figure may be amended. The figure number in the amended drawing should not be labeled as "amended."

For further information on the prototype image electronic processing of patent applications, please contact the Search and Information Resources Administration at: **image.processing@uspto.gov**. Any questions regarding the submission of amendments pursuant to the revised practice set forth in this notice should be directed to Elizabeth Dougherty (**Elizabeth.Dougherty@uspto.gov**), Gena Jones (**Eugenia.Jones@uspto.gov**) or Joe Narcavage (mailto:**Joseph.Narcavage@uspto.gov**). For information on the waiver or legal aspects of the program, please contact Jay Lucas (**Jay.Lucas@uspto.gov**) or Rob Clarke (**Robert.Clarke@uspto.gov**).

Date: 1/31/03

Signed: /s/_____
STEVEN KUNIN
Deputy Commissioner for Patent
Examination Policy

CALBIOCHEM®

EMPIGEN BB® Detergent, 30% Solution

	Size
Cat. No. 324690	100 ml

Synonym: *n*-Dodecyl-N,N-dimethylglycine

Description: A zwitterionic detergent. Lauryldimethylbetaine is useful as a detergent for solubilization of membrane components and for preparation of viral agents. Also useful for the solubilization of keratins. Has a critical micellar concentration of 1.6-2.1 mM.

Form: Liquid. Supplied as a 30% aqueous solution (w/w) or 1.14M.

Molecular Weight: 272.0

Molecular Formula: $C_{16}H_{33}NO_2$

Solubility: H_2O

Storage: Room temperature (+20°C). This product is stable for 3 years as supplied.

Toxicity: MSDS available upon request.

References:

Lowthert, L.A., et al. 1995. *Biochem. Biophys. Res. Commun.* **206,** 370.

Mukklis, F.A., et al. 1986. *Vaccine* **4,** 191.

James, L.T., and Heckels, J.E. 1991. *J. Immunol. Methods* **42,** 223.

FOR RESEARCH USE ONLY. NOT FOR HUMAN OR DRUG USE.

Australia	Germany	Japan	United Kingdom	USA, Canada, Mexico
Tel (02) 9318 0322	Tel 0800 6931 000	Tel (03) 5443 0281	Tel 0115 9430 840	Tel (800) 628-8470

E-mail address for technical inquiries: technical@calbiochem.com
Find our current product data sheets on the web: http://www.calbiochem.com

Revised: 04-Jan-99